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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,297	03/03/2000	Moon Young Lim	4600-0130.30	5390
22918	7590	03/31/2006	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/518,297	Applicant(s) LIM ET AL.	
	Examiner Chih-Min Kam	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52, 53 and 60-63 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 52 and 53 is/are allowed.
 6) ☒ Claim(s) 60-63 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The instant application has been withdrawn from issue (see the notice dated February 1, 2006), and an office action follows.

Status of the Claims

2. Claims 52, 53 and 60-63 are pending.

Applicants' amendment to drawings filed October 5, 2005 is acknowledged. Claims 52, 53 and 60-63 are examined.

Withdrawn Objection to Drawings

3. The previous objection of to Figs. 2A and 2B is withdrawn in view of applicants' submission of formal drawings in the amendment filed October 5, 2005.

Objection to New Matter Added to Specification

4. The preliminary amendment filed May 22, 2000 and amendment filed May 12, 2005 are objected to under 35 U.S.C. 132 because they introduce new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The original specification does not disclose

TAPITDVSLGDELRLDGEEVDMTPMMDDFDLEMLGDVESPSPGMTHDPVSYGMD

VDDFEFEQMFTDALGIDDFG as SEQ ID NO:8 and

ADALDDFDLEMADALDDFDLEMADALDDFDLEMADALDDFDLEM as SEQ ID NO:9 in the Sequence Listing Table (see amendment filed May 12, 2005); and the amino acid sequences of SEQ ID NO:63 and 64 (for herpes simplex virus type 2 V16 Genbank Accession number

Art Unit: 1656

M57289) in the Sequence Listing Table (see amendment filed May 12, 2005), and Sequence Listing.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 60-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Bujard *et al.* (WO 94/29442).

Bujard *et al.* teach a system for regulating expression of eucaryotic genes using components of the Tet repressor/operator/inducer system of prokaryotes in a host cell, and transcription of a nucleotide sequence operably linked to at least one tet operator sequence is stimulated by a tetracycline (Tc)-controllable transcriptional activator fusion protein (tTA) which comprises two polypeptides, the first polypeptide is a Tet repressor (TetR), which binds to tet operator sequence in the absence of Tc, and the second polypeptide directly or indirectly activates transcription in eucaryotic cells, e.g., the second polypeptide can be a transcriptional activation domain from herpes simplex virus viron protein 16 (VP16) (page 2, lines 4-14), where in the absence of Tc, transcription of a gene operably linked to a tTA-responsive promoter (typically comprising at least one tet operator sequence and a minimal promoter) is stimulated by a tTA (page 2, lines 17-21). The reference also indicates a host cell can contain a polynucleotide moiety encoding a tTA and a gene of interest operably linked to a tTA-responsive transcriptional

Art Unit: 1656

promoter, where the gene of interest operably linked to the tTA-responsive transcriptional promoter can be integrated into DNA of the host cell either randomly (e.g., by introduction of an exogenous gene) or at a predetermined location (e.g., by targeting an endogenous gene for homologous recombination, the integration of polynucleotide encoding tTA and a tTA-responsive promoter, page 3, lines 24-39; claims 60-63), and expression of a gene of interest operably linked to a tTA-responsive transcriptional promoter in a host cell can be inhibited by contacting the cell with Tc (page 4, line 1-31; page 12, lines 19-37). The tTA in the absence of Tc is a DNA binding compound and modulates the binding of the transcriptional activation domain such as VP16 to the DNA response element, which meets the criteria of the claims.

Perhaps claims 60-63 can be amended as follows to differentiate from the prior art:

60. A molecular switch, comprising:

(a) a first nucleic acid construct, having

(i) a DNA response element for a transcriptional regulatory protein, operably linked to a first promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element, for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and

(b) a DNA binding compound, wherein the DNA binding compound is separate and different from the transcriptional regulatory protein; and

(c) a second nucleic acid construct, having the coding sequence for said transcriptional regulatory protein operably linked to a second promoter;

wherein said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element and wherein a first vector is including said first nucleic acid construct and a second vector is including said second nucleic acid construct.

61. A molecular switch, comprising:

(a) a first nucleic acid construct, having

(i) a DNA response element for a transcriptional regulatory protein, operably linked to a first promoter;

Art Unit: 1656

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element, for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and

(b) a DNA binding compound, wherein the DNA binding compound is separate and different from the transcriptional regulatory protein;

wherein said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element and wherein said compound binding sequence has from about 8 to 20 nucleotides.

62. A molecular switch, comprising:

(a) a first nucleic acid construct, having

(i) a DNA response element for a transcriptional regulatory protein, operably linked to a first promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element, for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and

(b) a DNA binding compound, wherein the DNA binding compound is separate and different from the transcriptional regulatory protein;

wherein said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element and wherein said nucleic acid construct has from 1 to 12 compound binding sequences.

63. A molecular switch, comprising:

(a) a first nucleic acid construct, having

(i) a DNA response element for a transcriptional regulatory protein, operably linked to a first promoter;

(ii) a non-native compound binding sequence which is the same as, overlapping, or adjacent to said DNA response element, for binding to a DNA binding compound;

(iii) a transgene under the control of said first promoter; and

(b) a DNA binding compound, wherein the DNA binding compound is separate and different from the transcriptional regulatory protein;

wherein said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element and wherein said nucleic acid construct has from 1 to 12 tandem repeated transcriptional regulatory protein DNA response elements.

Conclusion

5. Claims 60-63 are rejected. It appears claims 52 and 53 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



**CHIH-MIN KAM
PATENT EXAMINER**

CMK

March 24, 2006